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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,695	09/30/2004	Jean- Francois Durette	10328-1-P9	5694
23486 7590 04/02/2010 SHUTTLEWORTH & INGERSOLL, P.L.C. 115 3RD STREET SE, SUITE 500 P.O. BOX 2107 CEDAR RAPIDS, IA 52406			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3774	PAPER NUMBER
			NOTIFICATION DATE 04/02/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/711,695

Applicant(s)

DURETTE, JEAN- FRANCOIS

Examiner

William H. Matthews (Howie)

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2008 and 07 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 15-19, 23-25 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14, 20-22, 26-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Species A (Figures 1 and 5-8) in the reply filed on 11/7/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-11, 15-19, 23-25, and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/7/08.

Response to Arguments

Applicant's arguments filed 5-23-08 have been fully considered but they are not persuasive.

With respect to **Allen**, Applicant argues Allen lacks **an elongation** as claimed. Examiner disagrees because, as Applicant acknowledge at page 13, Allen includes four elongations whereby one of the elongations reads on the claimed elongation. Note the claims are not written in such a way as to require there not be more than one elongation. Applicant further argues Allen lacks **an stigmatism** as claimed. Examiner disagrees because the recitation of the respective sides of the implant and cavity are of intended use and considered nominal recitations which may be assigned to arbitrary sides of the device in Allen. See MPEP 2114. Arguments to **claim 16** are moot since

the claim is withdrawn, however Examiner maintains the structure of claim 16 is met by Allen in view of MPEP 2114.

With respect to **Finger**, Applicant argues **the portions are not separated into anterior and posterior portions** as defined by the patient's orbit. Examiner disagrees because the limitations regarding anterior and posterior are nominal and do not impart structure nor require a particular section of Finger to be designated anterior or posterior. Furthermore the limitation "portion" is further considered a broad descriptive term. With respect to claim 29, Examiner maintains the same argument.

With respect to **Hicks**, Applicant fails to argue claim 20. Applicant does argue that **Hicks lack tunnels and chimneys** as claimed because such structures in Hicks are used for a different purpose. Examiner disagrees and again refers to MPEP 2114 wherein it is described that the intended use of a claimed device does not structurally distinguish itself from the prior art when the prior art meets the recited structure and is fully capable of use as claimed. Examiner maintains that Hicks is fully capable of use as claimed as recited in claims 20-22 (note claim 23 is currently withdrawn). With respect to claim 26, Applicant argues **Hicks lack acrylic materials**. Examiner disagrees because Hicks disclose optional use of acrylics at column 4 line 54 - column 5 line 11.

With respect to the 103 rejection of **claim 7**, Applicant's arguments are moot as the amendment necessitates a new grounds of rejection.

Claim 18 has been cancelled, and **claims 24-25 and 30** are withdrawn.

Claim 31 is requested to be allowed but Applicant has not suggested how claim 31 overcomes by way of structural distinction over the art of record.

Applicant did not present any arguments as to the non-obviousness of claims 9-10 or 28. **Claims 9-10** are withdrawn, however the rejection of **claim 28** is presumed to be considered obvious by applicant for the reasons set forth in the previous office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 lines 7-10 may broadly interpreted to encompass asymmetric protrusions and openings or openings and protrusions that make the first or second portion asymmetric. The disclosure does not fully support the broad nature of the newly presented claim limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen USPN 3070808.

Allen disclose in figures 1-4 an orbital implant formed of one-piece acrylic and having a quasi-spherical shape and astigmatic features as claimed (see figures 2-3). The plurality of openings (as broadly claimed) are described at c3:28-55. Valleys, mounds, and a visible marking are shown in figure 1.

Claims 20,26,27,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Finger USPN 6419698.

Finger disclose in figures 5-6 an orbital implant comprising 2 pieces combined being implantation (c3:26-30). They may comprise silicone or acrylic (c3:64-65) and have a quasi-spherical shape defined by an elongation on one side (see figure 5).

Claims 20-22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hicks et al. USPN 6346121.

Hicks et al. disclose acrylic orbital implants comprising two pieces joined together and having tunnels and chimneys capable of tissue ingrowth and passage of sutures. See figures 2,5, c3:57-c5:4, and Examples 1,3, and 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8, 18, 20-22, 26-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen 3070808, as applied above, and in further view of Kelman USPN 4370760 and/or Hicks et al. USPN 6346121 and Rubin USPN 5466258 or Grip 20040039445.

Allen meet the limitations of claims 7-8, 18, 20-22, 26-29 as described above but lack the express written disclosure of using two separate parts or joining two parts by ultrasonic welding, and wherein the parts comprise asymmetric key (claim 31). Each of Kelman and Hicks teach ocular implants which may comprise unitary construction or separately constructed parts joined together. Kelman further teach the well-known use of ultrasonic welding. See Hicks c3:61-67 and Kelman c5:45-52. Furthermore, modifying a component into separately formed parts to be subsequently joined has been held to be within the realm of obvious design choice (*In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348,349 (CCPA 1961)). Also see MPEP 2144.04(V)(C). Still further, Hicks provide motivation to separate the parts in order to provide different properties along the device, and one of ordinary skill in the art would further realize a possible improvement in the manufacturing process in order to create the uniquely shaped

structure of Allen including tunnels and chimneys whereby the tunnels or openings are split amongst two parts that are joined (for example, if the device were divided in the top to bottom direction as shown in Figure 1).

With respect to the asymmetric key limitations of claim 31, Rubin show an ocular device (figure 5) which appears to have an asymmetric key opening and protrusion. Note the claim is interpreted as broadly encompassing a protrusion or opening that makes each respective part asymmetric about at least one axis. Although the disclosure of Rubin is silent as to the explicit teachings of Figure 5, the central asymmetric line of Figure 5 would reasonably teach that an asymmetric key would be appropriate for such devices. Furthermore, Grip teach a key (cover page) for ocular implants resulting in an asymmetric feature.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Allen by forming the device into separate parts, as taught by Kelman and/or Hicks and Rubin or Grip, in order to provide different properties along the length of the device or to improve the manufacturing process, and to further to join the parts by ultrasonic welding, as taught by Kelman, in order to securely join the parts, and to provide asymmetric key structures as taught in Rubin or Grip in order to provide a key structure to align the components.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finger 6419698 in view of Kelman USPN 4370760.

Finger meet the limitations of claim 28 as described above but lack the express written disclosure of using ultrasonic welding to attach the parts. Finger does disclose that adhesives may be used. Kelman teach ocular implant devices comprising multiple parts wherein they may be connected by adhesives or ultrasonic welding (c5:45-52) in order to securely fasten the parts.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Finger to include ultrasonic welding as taught by Kelman in order to securely fasten the parts.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774